Molluscan Shellfish Institute
a division of National Fisheries Institute

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June 22, 1999

To: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

From: The Coast-to-Coast Shellfish Consortium:
Pacific Coast Shellfish Growers Association
Gulf Oyster Industry Council
Louisiana Oyster Task Force
Maine Shellfish Growers
Molluscan Shellfish Institute

Subject: Parameter Identification for a Risk Assessment for *Vibrio parahaemolyticus* in Raw Molluscan Shellfish
Docket No. 99N-1075

The following comments are in response to the May 7, 1999 *Federal Register* notice on the Risk Assessment for *Vibrio parahaemolyticus*, and are being made jointly among the Pacific Coast Shellfish Growers Association (formerly the Pacific Coast Oyster Growers Association), the Gulf Oyster Industry Council, the Louisiana Oyster Task Force, the Maine Shellfish Growers and the Molluscan Shellfish Institute.

On May 26, 1999 when the Risk Assessment Task Force convened in Chicago, the commercial shellfish community in attendance at that meeting provided several comments and recommendations. Those comments are reiterated here, in addition to more specific concerns related to the published "Parameter Identification for a Risk Assessment on *Vibrio parahaemolyticus* in Raw Molluscan Shellfish" provided at the Chicago meeting.

We were told at the May 26 meeting that the timeline set for completion of the Risk Assessment (November 1999) must be adhered to due to deadlines imposed by the President's Food Safety Initiative. We would like to reiterate, for the record, that we believe too little scientific data and information will be available within this time-frame to craft a complete, well-reasoned risk assessment. Several studies currently being conducted on *V. parahaemolyticus* will provide critical information currently lacking, especially in regards to identifying pathogenic strains and infectious dose levels.

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We were assured that this initial assessment would be a 'living document' and provide merely the framework for continued modeling. However, we are concerned that policy decisions will be driven based on this November draft, given that it will be the most current and complete publication on the subject to date. If political pressure continues to mount, will the FDA be pressured into prematurely developing new rules? FDA should not allow this to happen. However, if this scenario were to occur this is undoubtedly the document policy makers would rely on. The shellfish community urges the Task Force and FDA officials to avoid premature policy actions based upon what is agreeably incomplete information.

Another concern we voiced at the Chicago meeting is the importance of not attempting to create a "One Size Fits All" Risk Assessment, given the significant differences found from coast to coast, from harvesting methods to environmental parameters to *V. parahaemolyticus* strains. It's equally important that public health officials charged with setting policy for the commercial shellfish industry not combine recreational and commercial harvest illness data. On the West Coast, a very significant number of the illnesses caused by *V. parahaemolyticus* have been traced to recreationally harvested product, which clearly commercial growers have no control over. While the organism may pose the same risk to the consumer regardless of harvest source, control methods for commercial versus recreational harvest may need to be quite different.

There are serious gaps in the scientific understanding of this organism as evidenced by the frequent referrals or recommendations in the "Parameter Identification" report to using "surrogate" organisms. This question is, in fact, posed in the report: "An over-riding question to be considered in this module is whether it is appropriate to apply what is known about the behavior of other Vibrio species in the environment and in shellfish to fill in existing information gaps for *V. parahaemolyticus*." (Page 5, first paragraph)

How can data gathered on *Vibrio cholerae* or *Vibrio vulnificus* be the scientific basis for determining what constitutes a risk for *Vibrio parahaemolyticus*? It is the stated intent of this Risk Assessment to "facilitate the evaluation of possible risk mitigation strategies" (page 31, Summary of "Parameters" report). Logic would suggest that basing the risk assessment for *V. parahaemolyticus* on anything other than the *V. parahaemolyticus* organism is inappropriate and merely a hypothetical exercise.

Much of the data presented at the meeting in Chicago and in the "Parameter" report has in fact combined Vibrio illnesses. The case series on "Vibrio" infections noted on page 23, paragraph 3, of the report has apparently combined all Vibrio illnesses. This is not useful information for the indicated purposes of this particular assessment.

We urge the Task Force to strive for consistency in the matter of data collection in the course of developing the risk assessment. For example, the manner in which illnesses were counted in the 1998 outbreak in Galveston Bay, Texas was very different than the methods that have been used on the West Coast. Illnesses in Washington include only

those that have been verified through a stool or blood sample. In the case of Texas, anyone with symptoms who placed a toll-free call was included in the "illness outbreak" numbers. Gathering data on the basis of unverified telephone reports is not appropriate or reliable data for a sound scientific risk assessment.

The commercial shellfish community is particularly concerned with statements made at the meeting in Chicago and in the "Parameters" report that implies it is FDA's intent to educate consumers to cease eating raw oysters altogether as a means of protecting public health. FDA staff Michael DiNovi stated this explicitly during his presentation at the Chicago meeting when he said: "Our education efforts must be working...[data from Florida] indicates the numbers of people willing to eat raw oysters has decreased by one-third from 1997 to 1998..." The report, too, is quite explicit in this regard. In the Introduction section, paragraph two, it states "The risk assessment will evaluate...b) the effectiveness of potential strategies for limiting exposure of the public to raw molluscan shellfish, particularly oysters contaminated with *V. parahaemolyticus*." This last statement is quite telling. The goal of public health agencies should be to limit consumer exposure *quite specifically* to *contaminated* oysters with a potential for causing illness, not to oysters in general.

Another concern that our industry has voiced in earlier letters, petitions and public comments is the very real possibility that the last two unusually hot summers have given rise to anomalous conditions that caused the illness outbreaks. We are concerned that public health policy is being crafted as if these conditions are the norm. The *V. parahaemolyticus* illness outbreak in Texas, being used as an example of the need for stricter control methods was another anomaly. The *V. parahaemolyticus* in this outbreak proved to be a strain native to India, never before seen in U.S. coastal waters, and strongly suspected to have arrived via ship ballast water. Therefore, this outbreak should not be used as a basis for stricter controls.

As noted during the Public Comment period at the end of the Chicago meeting, shellfish industry members were concerned with lack of accurate data, and urged the Task Force to communicate with us to assure production numbers and illness data for each region are accurate. To date, none of us have been contacted for this information. Since a draft of the Risk Assessment is due in September, we would once again urge members to contact us directly and soon to assure the numbers and information on harvesting methods is correct. A list of contacts for each region is attached here.

As an industry, we have voiced repeatedly that there is a dangerous precedence being set by FDA in handling shellfish safety issues outside of the appropriate venue of the Interstate Shellfish Sanitation Conference. The MOU between ISSC and FDA assures that these issues will be deliberated through the ISSC process. We would like to once again stress how important it is that the ISSC continue to be the process through which critical public health policies related to shellfish are developed. We understand the work of this Task Force will, eventually, go forward to the ISSC. That is appropriate and

certainly provides the best opportunity for achieving the industry compliance pivotal to assuring public health. However, we are distressed that there is no provision for industry participation in the risk assessment process.

Thank you for your consideration of these critical issues. As we stated in Chicago, the commercial shellfish community is highly supportive of developing truly scientific monitoring and control methods for *V. parahaemolyticus* that will protect our customers. It is our hope that the Risk Assessment and subsequent studies will utilize the best scientific data and models available, so that public health will indeed be served.

Sincerely,

Robert Collette
Director
Molluscan Shellfish Institute
(signing for)
The Coast-to-Coast Shellfish Consortium:
Pacific Coast Shellfish Growers Association
Gulf Oyster Industry Council
Louisiana Oyster Task Force
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